Spurious drugs

†560. SHRIMATI KUM KUM RAI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware that spurious and sub-standard drugs are being sold dauntlessly in the country;

(b) whether it is also a fact that the Department Related Parliamentary Standing Committee on Petroleum and Chemicals has expressed concern over sale of sub-standard drugs;

(c) if so, the steps taken by Government to keep a check on manufacturing and sale of spurious and harmful sub-standard drugs; and

(d) the action taken against the guilty persons?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) As per the feedback available from the State Drug Controllers, 38824, 43138, 40862 drug samples were tested during the period 2001-2002, 2002-2003 and 2003-2004, out of which 96, 129 and 118 samples declared spurious and 3458, 3724 and 3499 samples declared sub-standard respectively. Therefore, 0.33 per cent, 0.29 per cent and 0.288 per cent of these samples reported spurious and 8.9 percent, 8.63 percent and 8.56 percent of samples reported sub-standard.

Overall the aforesaid data revealed that around 0.3 per cent of drugs were declared spurious and around 8.5-9 per cent drugs were declared as sub-standard. It may be relevant to mention that a drug may be declared sub-standard because of defects which may not affect the therapeutic efficacy of the drug.

(b) Yes, Sir.

(c) Manufacture of spurious/counterfeit/fake drugs is primarily a clandestine activity and trading in counterfeit products, including drugs, is reported world over. However, keeping in view the serious implications of spurious drugs on public health as well as the loss to genuine industry, the Government has taken the following measures to combat this menace:—

†Original notice of the question was received in Hindi.

(i) Detailed guidelines have been issued to the State Government to undertake focussed surveillance over possible movement of spurious drugs.

(ii) A Capacity Building Project through World Bank assistance has been taken up to provide substantial assistance to State Government to upgrade drug testing facilities or to establish new drug testing laboratories. It is expected to increase the number of samples tested in the country from about 36,000 samples to 1,00,000 samples per year and to reduce the reporting time to less than a month as against the present period from 3 to 6 months. In addition, the project envisages extensive training of the Central and State/UT drug regulatory staff and the concerned personnel from the Pharmaceutical Industry and a campaign for information, Education and Communication (IEC) for the consumers.

(iii) Specific training programmes for regulatory officials of State Government on logistics of intelligence work, prosecutions etc. has been conducted with the assistance of FDA, Maharashtra. This activity is proposed to be continued.

(iv) In order to ensure efficient information exchange between drug regulatory officers in the country, in respect of licensing, sampling, prosecution, etc., a countrywide computer networking project has been undertaken by the Central Government This will enable the Central Government to regularly monitor the enforcement activities and recommend corrective measures.

(v) Pharma industry and traders have been motivated to fight the menace of spurious drugs as a shared responsibility. A number of cases could be successfully detected through the initiative taken by pharma industry involving hiring of retired intelligence officers.

(d) Under the Drugs and Cosmetics Act, 1940, the responsibility for regulating the manufacture and sale of drugs including taking legal action against the unscrupulous persons rests with the State Governments. As per the feedback available from the State Drug Controllers, 538, 449 and 570 prosecutions were launched and 171, 105 and 166 cases were decided during, the period 2001-2002, 2002-2003 and 2003-2004 respectively.